



## Clinical Edit Criteria Proposal

Drug/Drug Class: **Provigil® (Modafanil) and Nuvigil® (Armodafanil)**  
Clinical Edit  
Date: **August 27, 2013**  
Prepared for:  
Prepared by: **MO HealthNet**

☐ New Criteria

☒ Revision of Existing Criteria

### Executive Summary

**Purpose:** To ensure appropriate utilization and control of Provigil® (Modafanil tablets) and Nuvigil® (Armodafanil tablets).

**Why was this Issue Selected:**

Provigil® and Nuvigil® are branded drug products indicated to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea, narcolepsy and shift work disorder. Narcolepsy is not rare, but it is an underrecognized and underdiagnosed condition. The disorder is estimated to affect about one in every 2,000 Americans, but the exact prevalence rate remains uncertain and the disorder may affect a larger segment of the population. Narcolepsy appears throughout the world in every racial and ethnic group, affecting males and females equally, but prevalence rates vary among populations. Compared to the U.S. Population, for example, the prevalence rate is substantially lower in Israel (about one per 500,000) and considerably higher in Japan (about one per 600). Sleep apnea is very common, as common as adult diabetes, and affects more than twelve million Americans, according to the National Institutes of Health. Obstructive sleep apnea (OSA) is caused by a blockage of the airway, usually when the soft tissue in the rear of the throat collapses and closes during sleep. With each apnea event, the brain briefly arouses people with sleep apnea in order for them to resume breathing, but consequently sleep is extremely fragmented and of poor quality. Millions of Americans are shift work employees and if their shift hours change frequently a shift work sleep disorder may develop. The number of Americans with a shift work sleep disorder has not been determined. All three of these sleep disorders can lead to serious consequences if not treated.

**Program-specific information:**

Drug	Claims	Costs
Provigil 100 mg tablets	186	\$160,655
Provigil 200 mg tablets	834	\$897,726
Nuvigil 50 mg tablets	74	\$15,584
Nuvigil 150 mg tablets	451	\$229,978
Nuvigil 250 mg tablets	623	\$300,381
Totals	2,168	\$1,604,324

July 1, 2012 – June 30, 2013 - FFS Claims

**Setting & Population:**

Patients 16 years of age and older

**Type of Criteria:**

☐ Increased risk of ADE

☐ Non-Preferred Agent

☒ Appropriate Indications

☐ Other:

**Data Sources:**

☐ Only administrative databases

☒ Databases + Prescriber-supplied

## Setting & Population

- Age range: Modafinil age  $\geq 16$  and Armodafinil age  $\geq 17$
- Gender: males and females

## Approval Criteria

- History of narcolepsy, obstructive sleep apnea, work shift disorder, or hypersomnia, or fatigue related to multiple sclerosis in the past 2 years (See Appendices for specific codes)
  - Obstructive sleep apnea diagnosis requires history of CPAP
  - Multiple sclerosis requires trial of amantadine in past year
- Lack of history of stimulant use in past 90 days
- Compliance 90/120 days

## Denial Criteria

- Claims for patients under 16 years of age for modafinil and <17 years of age for armodafinil (require clinical consultant review)
- Patients do not meet approval criteria
- History of stimulant use in past 90 days
- Dosage exceeds FDA limit



## Required Documentation

Laboratory results:

☒

MedWatch form:

☐

Progress notes:

☐☐

## Disposition of Edit

- **Denial:** Edit 682 "Clinical Edit"

## References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2010.
2. Facts and Comparisons; 2010.
3. Package Insert for Provigil, Cephalon, Inc., Frazier, PA 19355; 2010
4. Package Insert for Nuvigil, Cephalon, Inc., Frazier, PA 19355; 2010
5. USPDI, Micromedex, 2010.



## Appendix A

Drug	Unit Limit Per Day
Provigil 100 mg tablets	2
Provigil 200 mg tablets	2
Nuvigil 50 mg tablets	1
Nuvigil 150 mg tablets	1
Nuvigil 250 mg tablets	1

## Appendix B

Diagnosis codes used to identify positive history of narcolepsy in the past 2 years.

ICD-9-CM diagnosis	Code Description	ICD-10-CM diagnosis	Code Description
347.00	Narcolepsy, without cataplexy	G47.419	Narcolepsy without cataplexy
347.01	Narcolepsy, with cataplexy	G47.411	Narcolepsy with cataplexy
347.10	Narcolepsy in conditions classified elsewhere, without cataplexy	G47.429	Narcolepsy in conditions classified elsewhere without cataplexy
347.11	Narcolepsy in conditions classified elsewhere, with cataplexy	G47.421	Narcolepsy in conditions classified elsewhere with cataplexy

## Appendix C

Diagnosis Codes used to identify positive history of Obstructive Sleep Apnea in the past 2 years.

ICD-9-CM diagnosis	Code Description	ICD-10-CM diagnosis	Code Description
327.23	Obstructive sleep apnea (adult)(pediatric)	G47.33	Obstructive sleep apnea (adult) (pediatric)

## Appendix D

Diagnosis codes used to identify positive history of shift work disorder in the past 2 years.

ICD-9-CM diagnosis	Code Description	ICD-10-CM diagnosis	Code Description
327.36	Circadian rhythm sleep disorder, shift work type	G47.26	Circadian rhythm sleep disorder, shift work type



## Appendix E

Diagnosis codes used to identify positive history of hypersomnia in the past 2 years

ICD-9-CM diagnosis	Code Description	ICD-10-CM diagnosis	Code Description
780.53	Hypersomnia with sleep apnea, unspecified	G47.10	Hypersomnia, unspecified
780.54	Hypersomnia, unspecified	G47.11	Idiopathic hypersomnia with long sleep time
		G47.12	Idiopathic hypersomnia without long sleep time
		G47.13	Recurrent hypersomnia
		G47.14	Hypersomnia due to medical condition
		G47.19	Other hypersomnia

## Appendix G

Procedure codes used to identify positive history of CPAP in the past 2 years.

Code	Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
95811	Polysomnography; sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist
E0601	Continuous airway pressure (CPAP) device
93.90	Continuous positive airway pressure (CPAP)

## Appendix H

Diagnosis codes used to identify positive history of multiple sclerosis in the past 2 years.

ICD-9-CM diagnosis	Code Description	ICD-10-CM diagnosis	Code Description
340	Multiple Sclerosis	G35	Multiple Sclerosis

